## **Newborn Screening Quality Assurance Program**

Second-tier Congenital Adrenal Hyperplasia Quality Control Specimen Certification Set 2— July 11 2016

## Analysis Method: LC-MS/MS Material Expiration Date: August 2017

ENRICHMENT LEVELS (endogenous levels not included)

Lot (ng/mL serum)	17α-Hydroxyprogesterone (17OHP2)	4-Androstenedione (4AD2)	Cortisol (CORT2)	11-Deoxycortisol (11D2)	21-Deoxycortisol (21D2)
A1611	0	0	0	0	0
B1611	10	10	10	10	10
C1611	50	50	50	50	50
D1611	100	100	100	100	100
E1611	500	500	500	500	500

## **ANALYTICAL INFORMATION**

Lot Numbers, Mean Values $(x)$ , and 95% Confidence Limits $(CL)$ . Units are $ng/mL$ serum.								
Lot	17α-Hydroxyprogesterone (17OHP2)	4-Androstenedione (4AD2)	Cortisol (CORT2)	11-Deoxycortisol (11D2)	21-Deoxycortisol (21D2)			
	Mean/ 95% CL	Mean/ 95% CL	Mean/ 95% CL	Mean/ 95% CL	Mean/ 95% CL			
A1611	$\bar{x} = 2.3$ CL = 0.0 - 7.0	$\bar{x} = 0.7$ CL = 0.0 - 1.8	$\bar{x} = 2.5$ CL = 0.0 - 5.5	$\bar{x} = 3.0$ CL = 1.3 – 4.7	$\bar{x} = 1.3$ CL = 0.0 – 3.0			
B1611	$\bar{x} = 11.9$ CL = 8.7 - 15.2	$\bar{x} = 9.6$ CL = 6.3 - 13.0	$\bar{x} = 14.0$ CL = 9.3 - 18.6	$\bar{x} = 13.8$ CL = 10.7 - 17.0	$\bar{x} = 13.4$ CL = 8.7 - 18.0			
C1611	$\bar{x} = 55.4$ $CL = 40.9 - 70.0$	$\bar{x} = 50.3$ CL = 35.6 - 65.0	$\bar{x} = 63.1$ CL = $50.8 - 75.5$	$\bar{x} = 55.2$ CL = 42.4 - 68.0	$\bar{x} = 59.1$ CL = 48.9 - 69.2			
D1611	$\bar{x} = 97.0$ CL = 67.0 - 127.0	$\bar{x} = 90.9$ CL = 65.2 - 116.7	$\bar{x} = 116.4$ CL = 96.3 - 136.4	$\bar{x} = 101.4$ $CL = 80.4 - 122.4$	$\bar{x} = 118.8$ CL = 88.7 - 148.8			
E1611	$\bar{x} = 508.8$ CL = 369.6 - 648.0	$\bar{x} = 474.1$ $CL = 354.6 - 593.6$	$\bar{x} = 564.5$ $CL = 482.5 - 646.6$	$\bar{x} = 494.3$ $CL = 408.9 - 597.7$	$\bar{x} = 604.5$ $CL = 467.0 - 742.0$			

**Note:** The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.